## REMARKS/ARGUMENTS

Applicant respectfully request reconsideration of this application in view of the following remarks.

### Nonstatutory Obviousness-type Double Patenting Rejection

The Office has rejected claims 1-39 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patent No. 6,611,846 (Stoodley), and states on page 2:

> "A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
>
> Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b)." Office Action Page 2, ¶1.

### Response to Nonstatutory Obviousness-type Double Patenting Rejection

In response, Applicant timely files a terminal disclaimer in compliance with 37 CFR 1.321(c) to remove this ground for rejection.

### Response to Rejection of Claims 1, 3, 4, 6 under 35 U.S.C. § 102(e) – Barry

The Office has rejected claims 1, 3, 4, and 6 under 35 U.S.C. 102(e) as being anticipated by Barry et al (Barry), US 5,991,729, 23 November 1999:

"Barry is directed to generating patient-specific medical reports that include diagnostic analysis, which corresponds to analyzing healthcare data [COL 1 lines 5-18].

As to **claim 1:**

The claim as a whole is taught essentially as claimed in Barry at COL 2 line 66 to COL 3 line 62. In more particular:

Barry uses a relational database to maintain data sets specific to a particular patient [FIG 1; COL 1 lines 10-13]. A patient identifier is used [COL 2 line 67]. It is inherent in a relational database system that data is maintained in tables, organized by criteria (column designators). [See also COL 1 line 67 to COL 2 line 3].

Barry manages data in the categories of diagnosis [COL 2 lines 32-34] and outcomes in the form of reports [COL 2 lines 49-59], treatment COL 3 lines 13-18] [sic], all of which are identified by patient.

Archival information concerning groups common to a diagnosis at least is determined in order to display a report (which corresponds to a presentation). See, for instance, the example of Barrett's Esophagus [COL 4 lines 27-52].

As to claim 3, the Barrett's Esophagus example of Col 4 lines 26-52 is a diagnosis category of pathological examination results. As to claim 4, Barry sets forth treatment categories for this disease in the passage cited.

As to claim 6, Barry includes multimedia data in the database and reports [COL 4 lines 21-26]." (Office Action, page 3-4.)

Applicant respectfully submits that with respect to the 35 U.S.C. 102 (e) rejections, the Office has not made out the required *prima facie* case of anticipation with the Barry reference.

A *prima facie* case of anticipation is established when the Office provides:

1. a single prior art reference
2. teaches or enables

3. each of the claimed elements (arranged as in the claim)
4. expressly or inherently
5. as interpreted by one of ordinary skill in the art.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California,* 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)., *Scripps Clinic & Research Found. v. Genentech Inc.,* 927 F.2d 1565, 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991). MPEP §2131. "The identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.,* 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Applicant's claim 1 reads:

"1. A method of analyzing healthcare patient data, the method comprising:

providing a database including patient data of data sets, each data set being for a different patient and having a unique patient identifier, the patient **data being located in tables of categories including at least two of diagnosis, treatment, and outcome**, wherein the patient data within the categories are stored as selected data options and the patient data of a data set relate by the patient identifier;

receiving at least one criterion for patient data located in at least one category;

determining patient data results for **all data sets in a group common to the criterion**; and

presenting the patient data results."

With respect to the Barry reference, the Barry reference does not teach each element of Applicant's claim 1. Barry teaches ".... generating a report that contains medical counseling information which is **specific to a patient**. The medical information is dependent upon the diagnostic analysis of a biological sample from **the patient**." (Barry, COL 1, lines 5-18.) Hence, Barry's report is specific to "a patient." Barry does not provide a method of extracting data pertaining to a plurality of patients which have a common criterion. Specifically, Barry does not teach, as Applicant teaches:

> "determining patient data results for **all data sets in a group common to the criterion.**" (Applicant's Claim 1.)

Barry's data base entries are based on an analysis of a single biological sample for a patient that is entered into Barry's data base from which a report can be generated for a single patient. (Barry, COL 2, lines 60 – COL 3 lines 13.)

Barry does not teach a data base that contains categories of data having subcategories, such as "diagnosis," "treatment," and "outcome." Specifically, Barry does not teach, as Applicant teaches: "**data being located in tables of categories including at least two of diagnosis, treatment, and outcome**;" (Applicant's Claim 1.) Barry does not teach these aspects of Applicant's invention because Barry is directed to extracting data from its data base for a single patient at a time based on a single analysis of a biological sample.

Since Barry does not teach all of the elements of Applicant's claim 1, Barry cannot serve as an anticipatory reference under 35 U.S.C. 102(e) and the rejection should be removed.

With respect to claims 3, 4, and 6 which depend from claim 1, Barry cannot serve as an anticipatory reference to these claims because Barry does not teach each and every

element of claims 3, 4, and 6 since these dependent claims include the limitations of base claim 1 by definition. Thus, since Barry does not teach all of the elements of Applicant's claim 3, 4, and 6, Barry cannot serve as an anticipatory reference under 35 U.S.C. 102(e) and the rejection should be removed.

**Claim Rejection under 35 U.S.C. § 103(a)**

The Office states on page 4 of the Office Action:

> "This application currently names **joint inventors**. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a)."

**Response to Claim Rejection under 35 U.S.C. § 103(a)**

In response to the paragraph directly above, common ownership was in effect as to all claims at the time of the making of the later invention.

**Response to Rejection of Claims 2, 5, 7-12 and 30-39 under 35 U.S.C. § 103(a)**

The Office has rejected claims 2, 5, 7-12, and 30-39 under 35 U.S.C. 103(a) as being unpatentable over Barry et al. (Barry), (US 5,991,729).

Respectfully, Applicant points out that since Barry cannot serve as an anticipatory reference under 35 U.S.C. 102(e) to claim 1, as well as the claims depending therefrom, in light of the arguments stated above, neither can Barry alone, provide a grounds for rejection under 35 U.S.C. 103(a).

Applicant respectfully points out that according to the MPEP §2142, "to establish a *prima facie* case of obviousness, three basic criteria must be met:

- 1st there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings;
- 2nd there must be a reasonable expectation of success;
- 3rd the prior art reference (or references when combined) must teach or suggest all of the claim limitations."

These criteria have not been met by the Office's rejection of Applicant's claims 2, 5, 7-12, and 30-39.

With respect to claim 2, Applicant teaches "each **symbolic code** represents a descriptor in more than one language." The Office states:

> **It would have been obvious** to one of ordinary skill in the art at the time of the invention to provide for Latin as well as a native language because it supports standard and precise descriptions. (Office Action, page 5.)

A "symbolic code" is not equivalent to the Latin language nor is a "symbolic code" cast in any particular language, it is just that, a "symbolic code" that is language independent. The Office's proffered use of Latin in conjunction with a native language is not equivalent to Applicant's symbolic code.

**Applicant challenges the factual assertion as Not Properly Officially Noticed or not Properly Based Upon Common Knowledge.**

From the MPEP §2144.03(E): "Any rejection based on assertions that a fact is well-known or is common knowledge in the art without documentary evidence to support the examiner's conclusion should be judiciously applied. Furthermore, as noted by the court in *Ahlert*, any facts so noticed should be of notorious character and serve only to 'fill in the gaps' in an insubstantial manner which might exist in the evidentiary showing made by the examiner to support a particular ground for rejection. *See, for example, In re Zurko*, 258 F.3d 1379, 1386; *In re Ahlert*, 424 F.2d 1088, 1092."

Further, "[a]s noted by the court in *In re Ahlert*, 424 F.2d 1088, 1091 (CCPA 1970), the notice of facts beyond the record which may be taken by the examiner must be 'capable of such instant and unquestionable demonstration as to defy dispute.' (citing *In re Knapp Monarch Co.*, 296 F.2d 230, 132 USPQ 6 (CCPA 1961))." MPEP §2144.03.

Claim 2: Claim 2 recites, *inter alia*:

"each **symbolic code** represents a descriptor in more than one language"

The Office Action asserts without any basis or support:

> "**It would have been obvious** to one of ordinary skill in the art at the time of the invention to provide for Latin as well as a native language because it supports standard and precise descriptions." (Office Action, page 5.)

Claims 5, and 7-12: Claims 5, and 7-12 recite:

> "5. The method of claim 1, wherein the outcomes category includes at least one of clinic visit outcomes score, admissions outcomes score, discharge outcomes score, complication, disability and cause of death factor category.

7. The method of claim 1, further comprising creating a report for at least two of audit, mortality and morbidity, reporting, discharge list, and accreditation case log.

8. The method of claim 1, wherein the patient data results are related to at least two tasks of a group of tasks consisting of patient management, clinical outcomes tracking, healthcare research, training of healthcare professionals, fulfilling certification or accreditation requirements, clinical trials, quality improvement assessment, informed consent tracking, risk mitigation assessment, access to multimedia files linked to treatment events, data collection for export to other database systems, and billing.

9. The method of claim 8, wherein the patient data results is related to at least three of the tasks.

10. The method of claim 8, further including transferring the patient data results to a form for patient management, clinical outcomes tracking, fulfilling certification or accreditation requirements, clinical trials, quality improvement assessment, informed consent tracking, risk mitigation assessment, and billing.

11. The method of claim 1, wherein the patient data results include at least one level of a category hierarchical tree having data options arranged in increasing levels of specificity.

12. The method of claim 11, wherein the patient data results include patient data common to the received criterion and criterion from lower levels of the hierarchical tree."

The Office Action asserts without any basis or support:

> "As to **claim 5**, Barry does not explicitly list the scores and effects as cited, but **it would have been obvious** to one of ordinary skill in the art at the time of the invention to provide for them because they are useful components of extended treatments and of diagnostic data. Including the elements of **claims 7-9** into the system of Barry would have been obvious to one of ordinary skill in the art for similar reasons. They fall within the category of in tended [sic] applications of the invention to specific data that would have been useful as support for the diagnosis reporting of Barry. Using claim 8 as exemplary, treatment regimes are tasks of patient management, the archival information relating to an example such as Barrett's is useful for training of healthcare professionals and/or certification of those tested for diagnostic abilities, and so on. Multimedia files have been addressed above.
>
> As to **claims 11 and 12**, it was well known in the art at the time of the invention to arrange data in a hierarchical tree for purposes of searching such a manner that lower levels are of increasing specificity. The motivation for such an arrangement is the efficiency of a directed search.
>
> The elements of **claims 30-39** are rejected in the analysis above and these claims are rejected on that basis." (Office Action, page 5-6.)

Applicant contends that these are mere conclusory statements and an impermissible reliance on Official Notice. Applicant contends this is not of notorious character nor insubstantial, as asserted in the Office Action. Certainly, the features recited in claims 2, 5, 7-12, and 30-39 are not capable of "instant and unquestionable demonstration as to defy dispute." These features are neither "basic knowledge" nor "common sense." *In re Lee*, 277 F.3d 1338, 1345 (Fed. Cir. 2002) ("Deficiencies of the cited references cannot be remedied by the Board's general conclusions about what is 'basic knowledge' or 'common

sense.'"). Applicants contend that claims 2, 5, 7-12, and 30-39 recite substantive features that cannot be overcome with Official Notice.

**Response to Rejection of Claims 13-29 under 35 U.S.C. § 103(a)**

The Office has rejected claims 13-29 under 35 U.S.C. 103(a) as being unpatentable over Barry et al (Barry), US 5,991,729, 23 November 1999 in view of Schneiderman (Schneiderman), US 5,099,424, 24 March 1992.

Applicant respectfully points out that according to the MPEP §2142, "to establish a *prima facie* case of obviousness, three basic criteria must be met:

- 1st there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings;
- 2nd there must be a reasonable expectation of success;
- 3rd the prior art reference (or references when combined) must teach or suggest all of the claim limitations."

These criteria have not been met by the Office's rejection of Applicant's claims 13-29.

The Office states:

> "Barry does not address the use of a linking event identifier, although clearly any data dealing with a specific patient must identify that patient, no matter what category or table contains the data. Thus Barry must have some mechanism that provides the same functionality. Barry also does not address patient management explicitly.
>
> Schneiderman is directed to processing clinical data processing that tracks outpatient practice COL 1 lines 9-59]. [sic] This is an improvement on prior art that used a patient identifier stored in data records [FIG 26 for example], which inturn include management and

surgery records [COL 7 lines 31-39]. The events in Schneiderman include EKG and CXR records [COL 1 line 60 and after].

**It would have been obvious** to one of ordinary skill to use the linking mechanism of Schneiderman and his prior art in the patient specific medical reports of Barry because they link together data that is both specific to a patient and significant to diagnosis, treatment, and outcome.

The combination teaches the use linked records of the types set forth in both teachings, wherein a linking event identifier can be the patient ID. With this combination, the elements of the claims are rejected in the analysis above and these claims are rejected on that basis." (Office Action, pages 6-7.)

Respectfully, none of the art cited performs Applicants method process of:

"storing a linking event identifier for linking event data to link at least some of the patient data related to a **patient management cycle**" (Claim 13, and Claim 22.) "linking patient data of a data set from the categories for a patient management cycle" (Claim 30.)

In the cited art, use of a linking mechanism associates clinical data either with a single patient or a single provider, i.e., doctor. The cited art performs its "association" simply because the data pertains to a particular patient and not because the data is part of a Patient Management Cycle. In fact, the cited art neither solely or in combination teaches nor suggests in any way, a Patient Management Cycle. Applicant defines a Patient Management Cycle in ¶ 69 of the specification as:

"A patient's encounters from the first presentation for a particular healthcare issue until the absolute completion of treatment and follow-up may be tracked as a "**Patient Management Cycle**."

Note that a Patient Management Cycle can exist for years; include a large number of encounters with a plurality of health care providers and a plurality of doctors. Such a system cannot be provided by the cited art, the cited art specifically teaches one patient and one encounter from one health care provider.

The Office's assertion that the cited art provides the same "linking" as Applicant's invention is not correct. Such an action in the cited art, i.e., associating clinical data with a single patient or a single provider, is not equivalent to Applicant's teaching in claims 13, 22, and 30 as well as the claims that depend therefrom, i.e., 14-21, 23-29 and 31-35.

Applicant's claims link relevant data to a Patient Management Cycle. There is no mention of a Patient Management Cycle in the cited art at all, much less linking relevant data into this nonexistent cycle. The Office uses impermissible hindsight reasoning to opine that:

> "Thus Barry must have some mechanism that provides the same functionality. Barry also does not address patient management explicitly." (Office Action, page 6.)

There is no logical connection between the action taken in the cited art (linking data by its physical characteristics in patient, space, and time) and the association of data to its clinical characteristics as part of a Patient Management Cycle. Specifically, the cited art provides no mechanism to link related diagnoses as does Applicant. (See ¶ 91, ¶ 97, etc., Applicant's Specification.)

The cited art does not teach, among other things taught by Applicant, accurate analyses of a patient's outcomes. Analysis of a patient's outcomes, e.g., undertaken to compare the quality of care delivered to the patient, requires that all outcomes include

clinical linking data for related diagnosis, associated treatment, and interval of follow-up are linked to the outpatient visit, etc. (See ¶ 69, ¶ 78, ¶ 79, ¶91, ¶ 95, ¶ 97, etc., Applicant's Specification.)

All of the cited art teaches association of one patient and one health care provider. The art does not teach, as does Applicant in claim 21, storage and retrieval of data from more than one health care provider. A Patient Management Cycle can encompass health care received from a plurality of health care providers over a period of time; such a situation is not contemplated much less actually handled by the cited art.

The cited art of record does not teach all of Applicant's claim elements. Therefore, the Office has failed to make out the required prima facie case of obviousness required to sustain a 35 U.S.C. 103(a) rejection.

## CONCLUSION

Applicant submits that the rejection of dependent claims not specifically addressed, are addressed by Applicant's arguments to the claim(s) on which they depend.

Applicant respectfully submits that all claims are in condition for allowance and request such.

Communication via cleartext email is authorized.

Respectfully submitted,

PELOQUIN, PLLC

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Date

Mark S. Peloquin, Esq.
Mark S. Peloquin, Esq.
USPTO Registration # 50,787

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OCTOBER 2, 2006
Date